



Testimony

**Before the Committee on Government Reform,
Subcommittee on Federal Workforce and Agency
Organization**

U.S. House of Representatives

Activities of the Office of the National Coordinator for Health Information Technology

Statement of

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**For Release on Delivery
Expected at 9:30 a.m.
Wednesday, July 27 , 2005**

Chairman Porter and Members of the Subcommittee, I am Dr. David Brailer, the National Coordinator for Health Information Technology. The Office of the National Coordinator for Health Information Technology is a component of the Department of Health and Human Services (HHS). Thank you for inviting me to testify today on health information technology activities underway in the Department.

Setting the Context

On April 27, 2004, the President signed Executive Order 13335 (EO) announcing his commitment to the development and nationwide implementation of an interoperable health information technology infrastructure to improve efficiency, reduce medical errors, raise the quality of care, and provide better information for patients, physicians, and other health care providers. In particular, the President called for widespread adoption of electronic health records (EHRs) within 10 years so that health information will follow patients throughout their care in a seamless and secure manner. Toward that vision, the EO directed the Secretary of the Department Health and Human Services (HHS) to establish within the Office of the Secretary the position of National Coordinator for Health Information Technology (National Coordinator), with responsibilities for coordinating Federal health information technology (health IT) programs with those of relevant executive branch agencies, as well as coordinating with the private sector on their health IT efforts. On May 6, 2004, Secretary Tommy G. Thompson appointed me to serve in this position.

On July 21, 2004, during the Department's Health IT Summit, we published the "Framework for Strategic Action: The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care," (The Framework). The Framework outlined an approach toward nationwide implementation of interoperable EHRs and in it we identified four major goals. These goals are: 1) inform clinical practice by accelerating the use of EHRs, 2) interconnect clinicians so that they can exchange health information using advanced and secure electronic communication, 3) personalize care with consumer-based health records and better information for consumers, and 4) improve public health through advanced bio-surveillance methods and streamlined collection of data for quality measurement and research. The Framework has allowed many industry segments, sectors, interest groups, and individuals to

review how health IT could transform their activity or experience, consider how to take advantage of this change, and to participate in ongoing dialogue about forthcoming efforts. My office has obtained significant additional input concerning how these four goals can best be met.

- We have consulted with, and actively partnered with, numerous federal agencies in the U.S. Government including the Departments of Veterans Affairs, Defense, Commerce, and Homeland Security.
- We have met with many organizations and individuals representing stakeholders of the healthcare system to obtain their individual views.
- We have reached out to states and regions through site visits and town hall meetings to understand the health IT challenges experienced at the local level as well as best practices for the use of, and collaboration regarding, health IT.
- We have regularly testified before, and been informed by, the National Committee on Vital and Health Statistics (NCVHS) on issues critical to the nation's health IT goals.
- We have monitored, and coordinated with, the efforts of the Commission for Systemic Interoperability. (The Medicare Modernization Act called for the Secretary to establish the Commission to develop a comprehensive strategy for the adoption and implementation of health care information technology standards that includes a timeline and prioritization for such adoption and implementation.) and
- We have met with delegations involved with health IT from other countries, including Canada, Netherlands, Japan, Australia, Great Britain, and France to learn from their individual country experiences.

The *Framework for Strategic Action* and the Federal Health Architecture (FHA) are irrevocably linked in the effort to address critical health care needs. The FHA is now under the leadership of the ONC and will provide the structure or “architecture” for collaboration and interoperability among federal health efforts as specified in the *Framework for Strategic Action*. Moreover, the Consolidated Health Informatics activities are now moving forward under the FHA.

Building on the EO, The Framework, and this input, we have developed the clinical, business, and technical foundations for the HHS health IT strategy. Let me turn to some of those now.

The Clinical Foundation: Evidence of the Benefits of Health IT

We believe that health IT can save lives, improve care, and increase efficiency and potentially reduce costs in our health system. Five years ago, the Institute of Medicine (IOM) estimated that as many as 44,000 to 98,000 deaths occur each year as the result of medical errors. Health IT, through applications such as computerized physician order entry can help reduce medical errors and improve quality. For example, studies have shown that adverse drug events have been reduced by as much as 70 to 80% by targeted programs, with a significant portion of the improvement stemming from the use of health IT.

Every primary care physician knows what a recent study in the Journal of the American Medical Association (JAMA) showed: that clinical information is frequently missing at the point of care, and that this missing information can be harmful to patients. That study also showed that clinical information was less likely to be missing in practices that had full electronic records systems. Patients know this too and are taking matters into their own hands. A recent survey by the Agency for Health Care Research and Quality (AHRQ) with the Kaiser Family Foundation and the Harvard School of Public Health found that nearly 1 in 3 people say that they or a family member have created their own set of medical records to ensure that their health care providers have all of their medical information.

Some researchers estimate that savings from the implementation of health IT and corresponding changes in care processes could range anywhere from 7.5 percent of health care costs (Johnston et al., 2003; Pan et al, 2004) to 30 percent (Wennberg et al., 2002; Wennberg et al., 2004; Fisher et al., 2003; Fisher et al., 2003). These estimates are based in part on the reduction of obvious errors. For example, a medical error is estimated to cost, in 2003 dollars, about \$3,700 (Bates et al, 1997). However, these savings are not guaranteed through the simple acquisition of health IT. If poorly designed or implemented, health IT will not bring these benefits, and in some cases may even result in new medical errors and potential costs. Further, these are estimates which we have not yet seen realized in the health care system generally.

Therefore, achieving efficiency and potential cost savings requires a much more substantial transformation of care delivery that goes beyond simple error reduction. Health IT must be

combined with real process change in order to see meaningful improvements in our delivery system and systems must be standards compliant and interoperable so that patient information can be communicated to all possible points of care. It requires the industry to follow the best diagnostic and treatment practices everywhere in the nation. For example, cholesterol screenings can lead to early treatment, which in turn can reduce the risk for heart disease. Where that has been done, there have been substantial savings on cardiac expenditures.

So, this is the clinical foundation for our work, which demonstrates that health IT can save lives, improve care, and improve efficiency in our health system; now let me turn to the business foundation.

The Business Foundation: The Health IT Leadership Panel Report

Recognizing that the healthcare sector lags behind most other industries in its use of IT, an HHS contractor convened a Health IT Leadership Panel for the purposes of understanding how IT has transformed other industries and how, based upon experiences of members of the panel, it can transform the health care industry.

The Leadership Panel was comprised of nine CEOs from leading companies that purchase large quantities of healthcare services for their employees and dependents and that do not operate in the healthcare business. The Leadership Panel included CEOs from FedEx Corporation, General Motors, International Paper, Johnson Controls, Target Corporation, Pepsico, Procter & Gamble, Wells Fargo, and Wal-Mart Stores. The business leaders were called upon to evaluate the need for investment in health information technology and the major roles for both the government and the private sector in achieving widespread adoption and implementation. Based upon their own experiences using IT to reengineer their individual business – and by extension, their industries – the Leadership Panel concluded that investment in interoperable health IT is urgent and vital to the broader U.S. economy due to rising health care demands and business interests.

As identified by the Lewin Group, the Leadership Panel concluded:

- Potential benefits of health IT far outweigh manageable costs.
- Health IT needs a clear, broadly motivating vision and practical adoption strategy.

- The federal government should provide leadership, and industry will engage and follow.
- Lessons of adoption and success of IT in other industries should inform and enhance adoption of health IT.
- Among its multiple stakeholders, the consumer—including individual beneficiaries, patients, family members, and the public at large—is key to adoption of health IT and realizing its benefits.
- Stakeholder incentives must be aligned to foster health IT adoption.

The Leadership Panel identified as a key imperative that the Federal government should act as leader, catalyst, and convener of the nation's health information technology effort. The Leadership Panel also emphasized that federal leverage as purchaser and provider would be needed—and welcomed by the private sector. Private sector purchasers and health care organizations can and should collaborate alongside the federal government to drive adoption of health IT. In addition, the Leadership Panel members recognized that widespread health IT adoption may not succeed without buy-in from the public as health care consumer. Panelists suggested that the national health IT vision must be communicated clearly and directly to enlist consumer support for the widespread adoption of health IT.

These findings and recommendations from the Leadership Panel were published in a report released in May 2005 and laid the business foundation for the HHS health IT strategy. Now, let me turn to the technical foundation.

The Technical Foundation: Public Input Solicited on Nationwide Network

HHS published a Request for Information (RFI) in November 2004 that solicited public input about whether and how a Nationwide Health Information Network (NHIN) could be developed. This RFI asked key questions to guide our understanding around the organization and business framework, legal and regulatory issues, management and operational considerations, standards and policies for interoperability, and other considerations.

We received over 500 responses to the RFI, which were reviewed by a government-wide RFI Review Task Force. This Task Force was comprised of over 100 Federal employees from 17

agencies, including the Departments of Homeland Security, Defense, Veterans Affairs, Treasury, Commerce, Health and Human Services, as well as multiple agencies within the departments. The resulting public summary document has begun to inform policy discussions inside and outside the government.

We know that the RFI stimulated substantial and unprecedented discussions within and across organizations about how interoperability can really work, and we have continued to build on this. These responses have yielded one of the richest and most descriptive collections of thoughts on interoperability and health information exchange that has likely ever been assembled in the U.S. As such, it has set the foundation for actionable steps designed to meet the President's goal.

While the RFI report is an illustrative summary of the RFI responses and does not attempt to evaluate or discuss the relative merits of any one individual response over another, it does provide some key findings. Among the many opinions expressed by those supporting the development of a NHIN, the following concepts emerged:

- A NHIN should be a decentralized architecture built using the Internet, linked by uniform communications and a software framework of open standards and policies.
- A NHIN should reflect the interests of all stakeholders and be a joint public/private effort.
- A governance entity composed of public and private stakeholders should oversee the determination of standards and policies.
- A NHIN should provide sufficient safeguards to protect the privacy of personal health information.
- Incentives may be needed to accelerate the deployment and adoption of a NHIN.
- Existing technologies, federal leadership, prototype localized or regional exchange efforts, and certification of EHRs will be the critical enablers of a NHIN.
- Key challenges to developing and adopting a NHIN were listed as: the need for additional and better refined standards; addressing privacy concerns; paying for the development and operation of, and access to the NHIN; accurately verifying patients' identity; and addressing discordant inter- and intra-state laws regarding health information exchange.

Key Actions

Building on these steps, two critical challenges to realizing the President's vision for health IT are being addressed: a) interoperability and the secure portability of health information, and b) electronic health record (EHR) adoption. Interoperability and portability of health information using information technology are essential to achieve the industry transformation goals sought by the President.

To address these challenges, HHS is focusing on several key actions: harmonizing health information standards; certifying health IT products to assure consistency with standards; addressing variations in privacy and security policies that might pose challenges to interoperability; and, developing an architecture for nationwide sharing of electronic health information. HHS has allocated \$85 million to achieve these and other goals in FY 2005 and has requested \$125 million in FY 2006. These efforts are inter-related, and they will be coordinated through the formation of a new collaborative known as the American Health Information Community.

American Health Information Community (the Community)

On July 14, 2005, Secretary Michael Leavitt formally announced the formation of a national collaboration, the American Health Information Community (the Community), a public-private body formed pursuant to the Federal Advisory Committee Act. The Community is being formed for the purposes of helping transition the nation to electronic health records in a smooth, market-led way. The Community will provide input and recommendations to the Secretary on use of common standards and how interoperability among EHRs can be achieved while assuring that the privacy and security of those records are protected. And, it will be designed as an open, transparent and inclusive collaboration.

HHS is currently soliciting nominations for people to serve on the Community and Secretary Leavitt will appoint up to 17 commission members, including himself as chairperson. It will consist of nine members from the public sector and eight members from the private sector. Public Sector members will be drawn from Department of Health and Human Services

(including the Office of the Secretary, the Centers for Medicare and Medicaid Services, and the Public Health Service), Department of Veterans Affairs, Department of Defense, Department of Commerce, Department of the Treasury, Office of Personnel Management, and a State government representative. The private sector membership will be drawn from purchasers, third-party payers, hospitals, physicians, nurses, ancillary services (e.g., lab or pharmacy), consumer and privacy interests, and health information technology. Nominations for membership are being accepted through August 5, 2005. The Community is expected to be convened early this fall.

The Community will start by building on the vast amount of standardization already achieved inside and outside the healthcare industry. Specifically, the Community will:

- Make recommendations on how to maintain appropriate and effective privacy and security protections.
- Identify and make recommendations for prioritizing health information technology achievements that will provide immediate benefits to consumers of health care (e.g., drug safety, lab results, bio-terrorism surveillance, etc.).
- Make recommendations regarding the ongoing harmonization of industry-wide health IT standards and a separate product certification and inspection process.
- Make recommendations for a nationwide architecture that uses the Internet to share health information in a secure and timely manner.
- Make recommendations on how the Community can be succeeded by a private-sector health information community initiative within five years. (The sunset of the Community, after no more than five years, will be written into the charter.)

The Community will be chartered for two years, with the option to renew and duration of no more than five years. The Department intends for the Community to be succeeded within five years by a private-sector health information community initiative that, among other things, would set additional needed standards, certify new health information technology, and provide long-term governance for health care transformation.

In addition to the formation of the Community, the Office of the National Coordinator issued four requests for proposals (RFPs). The outputs of the contracts stemming from these RFPs will, in part, serve as inputs for the Community's consideration. We expect to award contracts based on these RFPs in September and October 2005. Specifically, the RFPs will focus on four major areas:

Standards harmonization

We have issued a Request For Proposal (RFP) to develop, prototype and evaluate a process to harmonize industry-wide standards development, and also unify and streamline maintenance of and refinements to existing standards over time. Today, the standards-setting process is fragmented and lacks coordination, resulting in overlapping standards and gaps in standards that need to be filled. We envision a process where standards are identified and developed around real scenarios – i.e., around use cases or breakthroughs. A “use case” is a technology term to describe how actors interact in specific value-added scenarios – for example, rapidly assembling complete patient information in an emergency room; we also call them “breakthroughs”.

Compliance certification

We have issued an RFP to develop, prototype and evaluate a process to specify criteria for the functional requirements for health IT products – beginning with ambulatory EHRs, then inpatient EHRs, and then the infrastructure components through which EHRs interoperate (e.g., NHIN architecture). This RFP will also evaluate a process for inspection based on conformance with these criteria.

NHIN Architecture

We have issued an RFP to develop models and prototypes for a NHIN for widespread health information exchange that can be used to test specialized network functions, security protections and monitoring, and demonstrate feasibility of scalable models across market settings. The NHIN architecture will be coordinated with the work of the Federal Health Architecture and other interrelated RFPs. The goal is to develop real solutions for nationwide health information exchange and ultimately develop a market – particularly the supply side – for health information exchange, which does not exist today. This RFP will fund 6 architectures and operational

prototypes that will maximize the use of existing resources such as the Internet, and will be tested simultaneously in three markets with a diversity of providers in each market. HHS intends to make these prototype architectures available in the public domain to prevent control of ideas and design. Through the RFP process, we encourage the development of a complete open source solution.

Security and privacy

We issued an RFP to assess variations in state laws and organization-level business policies around privacy and security practices, including variations in implementations of HIPAA privacy and security requirements that may pose challenges to automated health information exchange and interoperability. This RFP, administered by AHRQ, will seek to define workable mechanisms and policies to address these variations, while maintaining the levels of security and privacy that consumers expect.

Fraud and Abuse Study

In addition, HHS has a 6-month project underway to determine how automated coding software and a nationwide interoperable health information technology infrastructure can address healthcare fraud issues. The project is being conducted through a contract with the Foundation of Research and Education (FORE) of the American Health Information Management Association (AHIMA).

While only a small percentage of the estimated 4 billion healthcare claims submitted each year are fraudulent, the total dollars in fraudulent or improper claims is substantial. The National Health Care Anti-Fraud Association (NHCAA) estimates that healthcare fraud accounts for 3 percent of U.S. health expenditures each year, or an estimated \$56.7 billion. They cite other estimates, which may include improper but not fraudulent claims, as high as 10 percent of U.S. health expenditures or \$170 billion annually.

At present, the contractor is working to perform two main tasks. One task is a descriptive study of the issues and the steps in the development and use of automated coding software that enhance healthcare anti-fraud activities. The second task is identifying best practices to enhance the

capabilities of a nationwide interoperable health information technology infrastructure to assist in prevention, detection and prosecution, as appropriate, in cases of healthcare fraud or improper claims and billing. An expert cross-industry committee composed of senior level executives from both the private and public sectors is guiding this second task.

The project's final report is scheduled for completion in September 2005.

Conclusion

Thank you for the opportunity to present this summary of the activities of the Office of the National Coordinator for Health Information Technology. A year ago, the President created this position by Executive Order. In that time, we have established the clinical, business and technical foundations for the HHS health IT strategy. Now, we have begun to execute key actions that will give us real, tangible progress toward that goal.

HHS, under Secretary Leavitt's leadership, is giving the highest priority to fulfilling the President's commitment to promote widespread adoption of interoperable electronic health records – and, it is a privilege to be a part of this transformation.

This concludes my prepared statement. I would be delighted to answer any questions that you or the Members of the Subcommittee may have.